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| 10/596,512 | 06/15/2006 | Eddy Jean Edgard Freyne | PRD-2170USPCT | 7466 |
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| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | | |
| EXAMINER | | | | |
| JARRELL, NOBLE E | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,512

Applicant(s)

FREYNE ET AL.

Examiner

NOBLE JARRELL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 12 and 16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-5, 12, and 16 are pending in the current application. This is a National Stage of PCT/EP04/53501, filed 12/15/2004.
2. A new restriction is required because applicants have chosen the catch-all group. As shown in the original query run, the structure is too large to run to completion. **New group IX has been formed around the elected species in the reply filed 22 December 2008.**

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{CH}=\text{CH}=\text{N}-\text{CH}-$, Z is NH, X^2 is N-Ak, Y is Ak-C(O)N-Ak and X^1 is NR^{11} .

Group II, claim(s) 1-2, 4, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{CH}=\text{CH}=\text{N}-\text{CH}-$, Z is NH, X^2 is NC(O)Ak, Y is Ak- N-Ak and X^1 is NR^{11} .

Group III, claim(s) 1-2, 4, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{N}-\text{CH}=\text{CH}-\text{CH}-$, Z is NH, X^2 is NC(O)Ak, Y is Ak- N-Ak and X^1 is NR^{11} .

Group IV, claim(s) 1-2, 4, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{N}-\text{CH}=\text{CH}-\text{CH}-$, Z is NH, X^2 is Het²⁰-Ak where Het²⁰ is pyrrolidine, Y is C(O)N-Ak and X^1 is NR^{11} .

Group V, claim(s) 1-5, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{N}-\text{CH}=\text{CH}-\text{CH}-$, Z is NH, X^2 is O-Ak, Y is Ak-C(O)N-Ak and X^1 is NR^{11} .

Group VI, claim(s) 1-2, 4-5, 12, drawn to compounds and compositions of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{N}-\text{CH}=\text{CH}-\text{CH}-$, Z is NH, X^2 is N-Ak, Y is Ak-C(O)N-Ak and X^1 is NR^{11} .

Group VII, claim(s) 1-2, 4, 12, drawn to compounds, compositions, and a method of preparing compounds of formula I where a^1 - a^2 - a^3 - a^4 is $-\text{N}-\text{CH}=\text{N}-\text{CH}-$, Z is NH, X^2 is NC(O)Ak, Y is Ak-N-Ak and X^1 is NR^{11} .

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Group VIII, claims 1-5, 12, drawn to compounds, compositions, and a method of preparing compounds of formula I where a^1 - a^2 - a^3 - a^4 is $-N-CH=N-CH-$, Z is NH, X^2 is O, Y is C_6 -alkyl and X^1 is NR^{11} .

Group IX, claim(s) 1-5, 12, drawn to compounds, compositions, and a method of preparing compounds of formula I where a^1 - a^2 - a^3 - a^4 is $-N-CH=CH-CH-$, Z is NH, X^2 is O or O- C_{1-2} -alkyl, Y is C_{3-9} -alkyl or C_{3-9} -alkenyl and X^1 is NR^{11} .

Group X, claims(s) 1-5, 12, 16, drawn to compounds, compositions, and a method of preparing compounds of formula I not covered by groups I-IX

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common

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only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables Z, X², Y, and X¹ result in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

```

=> d que sta 19
19          STR
          13 18 14
          G4 G3 C
          20 11 12 15 16
          G2 C C C
          1 G1 2 7 6
          G1 C C N
          6 G1 4 10
          5

VAR G1=C/N
VAR G2=C/H/S
REP G3={0-4} A
REP G4={2-15} A
NODE ATTRIBUTES:
DEFAULT MLEVEL IS ATOM
DEFAULT ELEVEL IS LIMITED

GRAPH ATTRIBUTES:
RING(S) ARE ISOLATED OR EMBEDDED
NUMBER OF NODES IS 20

STEREO ATTRIBUTES: NONE

=> 19
STRUCTURE TOO LARGE - SEARCH ENDED
A structure in your query is too large. You may delete
attributes or atoms to reduce the size of the structure
and try again.

```

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

4. Inventions I-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different core ring structures or patentably distinct compounds. Inventions I-VIII are each patentably distinct because each invention represents a different core ring structure.

Claim 1 is generic to the following disclosed patentably distinct species: compounds of groups I-X. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (**for searching purposes only**) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If catchall group X is elected, further restriction may be necessary.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another

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species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a

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serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**